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PAPER

APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 10/769,686 01/30/2004 Lijun Xia 5920.002 9134 30589 7590 **EXAMINER** DUNLAP, CODDING & ROGERS P.C. PO BOX 16370 BELYAVSKYI, MICHAIL A OKLAHOMA CITY, OK 73113 ART UNIT PAPER NUMBER 1644 SHORTENED STATUTORY PERIOD OF RESPONSE MAIL DATE **DELIVERY MODE** 

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

12/22/2006

		Applicat	on No.	Applicant(s)	
		10/769,6	86	XIA ET AL.	
•	Office Action Summary	Examine	r .	Art Unit	
		Michail A	. Belyavskyi	1644	
	The MAILING DATE of this communi	cation appears on th	e cover sheet with the c	orrespondence address	
Period fo	• •	OD DEDLY 10 OFT :	TO EVOIDE AMOUNT I	0) 05 THETY (20) 5 AV	
WHIC - Exter after - If NO - Failu Any r	ORTENED STATUTORY PERIOD FO CHEVER IS LONGER, FROM THE Management of time may be available under the provisions of SIX (6) MONTHS from the mailing date of this comming period for reply is specified above, the maximum sta- re to reply within the set or extended period for reply only eply received by the Office later than three months at an adjustment. See 37 CFR 1.704(b).	AILING DATE OF T of 37 CFR 1.136(a). In no er unication. tutory period will apply and v will, by statute, cause the ap	HIS COMMUNICATION yent, however, may a reply be timused will expire SIX (6) MONTHS from plication to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).	
Status					
1)⊠	Responsive to communication(s) filed on 19/09/06.				
· ·	This action is <b>FINAL</b> . 2b)⊠ This action is non-final.				
3)□	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is				
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.				
Dispositi	on of Claims				
4)⊠	Claim(s) <u>14-19,22-41,55-60 and 63-91</u> is/are pending in the application.				
	4a) Of the above claim(s) is/are withdrawn from consideration.				
5)	Claim(s) is/are allowed.				
6)⊠	Claim(s) <u>14-19,22-41,55-60 and 63-91</u> is/are rejected.				
·	Claim(s) is/are objected to.				
8)	Claim(s) are subject to restrict	tion and/or election i	equirement.		
Applicati	on Papers				
9) The specification is objected to by the Examiner.					
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).					
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
Priority u	nder 35 U.S.C. § 119				
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).					
a) All b) Some * c) None of:					
	1. Certified copies of the priority documents have been received.				
	2. Certified copies of the priority documents have been received in Application No				
3. Copies of the certified copies of the priority documents have been received in this National Stage					
* 0	application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.				
3	ee the attached detailed Office action	Tion a list of the cert	med copies not receive	u.	
Attachment					
	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (P1	ro-948)	4) Interview Summary Paper No(s)/Mail Da		
3) 🛛 Inform	nation Disclosure Statement(s) (PTO-1449 or F No(s)/Mail Date <u>19/19/06</u> .			atent Application (PTO-152)	

Application/Control Number: 10/769,686

Art Unit: 1644

## RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 09/19/06 is acknowledged.

Claims 14-19, 22-41, 55-60, 63-91 are pending.

Claims 14-19, 22-41, 55-60, 63-91 read on a composition of fucosylated HSC are under consideration in the instant application.

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

In the response filed on 09/19/06, Applicant asserts that the title of the invention has been amended to be more indicative of the invention.

It is noted however, that there was no amended title in the response filed on 09/19/06.

- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Application/Control Number: 10/769,686

Art Unit: 1644

4. Claims 14-19, 22-41, 55-60, 63-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hidalgo et al (J Clin. Invest., 2002, Vol.110, pages 559-569, IDS) in view of Kobzdej et al (Blood, 2002, Vol.100 Pages 4485-4494 IDS).

Hidalgo et al., teach that homing of human HSCs comprising cells characterized as Cd34+Cd38<sup>low/-</sup> is impaired due to inability to bind with P –selectin or E-selectin ( see enite document, Abstract in particular). Hidalgo et al., further teach that said reduced ability to bind is due to a defect in the posttranslational processing of PSGL-1 protein that is expressed on the surface of said cells. Hidalgo et al., further teach that said posttranslational modification is fucosylation and that forsed fucosilation of said cells can be beneficial to improve homing of said cells. ( see overlapping pages 568-569 in particular). Hidalgo et al., further teach that improving homing of said cells would have many implications for therapies using human progenitor/stem cells, for example for transplantation.

Hidalgo et al., do not explicitly teaches a composition of fucosylated HSCs wherein fucosylated HSCs are produced by treating said cells in vitro with a 1,3 fucosyltransferase in the presence of a fucose donor.

Kobzdej et al., teach a method of forced fucosylation of intact WEHI-3 cells in vitro comprising treating said cells with a 1,3 fucosyltransferase in the presence of a fucose donor ( see entire document, Abstract in particular). Kobzdej et al., teach that said treatment will result in fucosylation of said cells that would enhanced their interaction with P-selectin or E-selectin.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply the teaching of Kobzdej et al., to those of Hidalgo et al., to obtain a claimed composition of fucosylated HSCs, wherein fucosylated HSCs are produced by treating said cells in vitro with a 1,3 fucosyltransferase in the presence of a fucose donor.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so, because forced fucosilation of cells by treating said cells with a 1,3 fucosyltransferase in the presence of a fucose donor would result in enhanced their interaction with P-selectin or E-selectin as taught by Kobzdej et al. Said treatment can be done to improve homing of human HSCs that would have many implications for therapies using human progenitor/stem cells, for example for transplantation as taught by Hidalgo et al. The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. In re Semaker. 217 USPQ 1, 5 - 6 (Fed. Cir. 1983). See MPEP 2144.

Claims 15-19, 23-27, 56-60 and 64-68 are included because claimed functional limitations would be an obvious properties of the fucosylated HSCs cells, because said fucosylated cells would be obtained by the same method as claimed.

Art Unit: 1644

From the combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

- 5. No claim is allowed.
- 6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/272-0841.

The fax number for the organization where this application or proceeding is assigned is 571/273-8300

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAIL BELYAVSKYI, PH.D. PATENT EXAMINER

12/08/06